#### **REMARKS**

#### Claim Amendments

Claims 1 and 4-10 are pending. Claim 10 is amended. Claims 12-27 are added. No new matter is added. Support for the claim amendments may be found in the application as originally filed. See, e.g., pages 7-10 and Examples.

### Withdrawn Objections and Rejections

Applicants appreciate the USPTO's indication that all previous rejections and objections are withdrawn.

### Claim Objections

Claim 7 stands objected to as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. The Office Action asserts that due to restriction requirement, "B is CH, so claim 7 is merely restating the limitation found within the restriction requirement."

Applicants respectfully traverse.<sup>2</sup>

Groups I-IV of the restriction requirement were directed to compounds and compositions of the formula (IA).<sup>3</sup> Group II was directed to compounds and compositions where B is CH.<sup>4</sup> Group III was directed to compounds and compositions where B is N.<sup>5</sup> Groups I-IV were subsequently combined into a single group.<sup>6</sup> Accordingly, the elected invention relates to compounds and compositions where B is either CH or N.

<sup>&</sup>lt;sup>1</sup> Office Action, page 3.

<sup>&</sup>lt;sup>2</sup> Applicants note this objection was previously made, addressed, and withdrawn. *See* Office Action dated October 25, 2007, page 4; Applicants April 25, 2008 response, pages 6 and 7; Final Office Action dated August 5, 2008, page 2 ("...any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn...")

<sup>&</sup>lt;sup>3</sup> See Restriction requirement, page 2.

<sup>&</sup>lt;sup>4</sup> *Id.* 

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> See Office Action dated October 25, 2007, page 2 ("Groups I-IV will be reduced to a single group containing compounds of Formula 1A…").

Claim 1 recites "B is N or CH." Claim 7 requires that "B is CH." Accordingly, claim 7 further limits claim 1.

In view of the foregoing, Applicants respectfully request withdrawal of this objection.

### Claim Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 112, second paragraph, because the USPTO requests clarification of the scope of "heteroaryl" and "heterocycloalkyl." The USPTO asserts that "Applicants' examples in the specification are not limited" and that "Applicants have not defined these terms with reasonable clarity." The USPTO also objects to the recitation of "heterobicycloalkyl," and "optionally substituted."

Applicants respectfully traverse this rejection. First, the USPTO improperly conflates breadth with indefiniteness. Second, "heteroaryl" and "heterocycloalkyl" are terms well known in the art; the specification's discussion of these terms would be readily understood by one of skill in the art. Third, "heterobicycloalkyl" and "optionally substituted" are not recited in the claims and therefore cannot render the claims indefinite. Accordingly, Applicants submit the claims are definite.

#### A. Breadth Is Not Indefiniteness

The USPTO contends that the claims are indefinite because the "examples in the specification are not limiting." This contention, however, is contrary to law. Indeed, it is well-settled that "breadth is not indefiniteness." Accordingly, simply because a claim covers numerous compounds does not render the claim indefinite.

<sup>&</sup>lt;sup>7</sup> Claim 7. (emphasis added).

<sup>&</sup>lt;sup>8</sup> Office Action, page 3.

<sup>&</sup>lt;sup>9</sup> *Id.* 

<sup>&</sup>lt;sup>10</sup> In re Gardner 166 USPQ 138, 140 (CCPA, 1970) ("Breadth is not indefiniteness"); In re Robins, 166 USPQ 552 (CCPA. 1970) (same) citing In re Gardner); Buell v. Beckestrom 22 USPQ2d 1128, 1133 (Bd. Pat. App. & Inter., 1992) (citing In re Gardner) ("While the claim language under consideration may be broad, breadth is not indefiniteness.").

## B. Heteroaryls And Heterocycloalkyls Are Well Known—One Of Skill In The Art Would Readily Understand The Specification's Discussion Of These Terms

The USPTO contends that "Applicants have not defined [heteroaryl and heterocycloalkyl] with reasonable clarity." 11

Applicants respectfully disagree. As an initial matter, Applicants point out that heteroaryls and heterocycloalkyls are well known in the art. Indeed, over *twelve thousand patents* recite either "heteroaryl" or "heterocycloalkyl" in the claims. <sup>12</sup> Accordingly, Applicants submit that one of skill in the art would readily understand what is meant by the recitation of "heteroaryl" and "heterocycloalkyl."

The specification defines "heteroaryl group" and "heterocycloalkyl group" as follows:

The term "heteroaryl group" is 5 to 7 membered monocyclic or polycyclic group thereof containing 2 to 8 carbon atoms and the same or different 1 to 4 hetero atom(s) such as oxygen, nitrogen or sulfur atom(s). The examples include pyrrole, furyl, thienyl, imidazolyl, thiazolyl, pyrazinyl, indolyl, quinolinyl, isoquinolinyl, tetrazolyl, pyridinyl, pyrazolyl, pyridazinyl, and pyrimidinyl. The "halogen atom" includes fluorine, chlorine, bromine and iodine.

The term "heterocycloalkyl group" is 3 to 7 membered heterocyclic group containing the same or different 1 to 4 hetero atom(s) such as oxygen, nitrogen or sulfur atom(s), and examples may include piperidinyl, pyrrolidinyl, piperazinyl, tetrahydrofuryl, tetrahydropyranyl, morpholinyl, azetidinyl, and homopiperazinyl.

Applicants submit that one of skill in the art would understand the metes and bounds of these terms. Indeed, the skilled artisan can readily envision, for example, 5 to 7 membered monocyclic or polycyclic groups containing 2 to 8 carbon atoms, and the same or different 1 to 4 hetero atoms. The specification's examples provides the skilled artisan with specific structures that fall within this definition. Accordingly, Applicants submit that there is no ambiguity in the recitation of "heteroaryl" and "heterocycloalkyl."

In the event the USPTO maintains this rejection, Applicants respectfully request that the USPTO specifically identify the purported ambiguity over the recitation of "heteroaryl" and "heterocycloalkyl."

<sup>&</sup>lt;sup>11</sup> Office Action, page 3.

 $<sup>^{12}</sup>$  See Search of USPTO patent database, attached as  $\mathbf{Exhibit}\,\mathbf{A}.$ 

### C. The Claims Do Not Recite "Heterobicycloalkyl" Or "Optionally Substituted"

The Examiner objects to the recitation of "heterobicycloalkyl" and "optionally substituted." These terms, however, are not present in the claims. Accordingly, Applicants request clarification as to this aspect of the rejection.

Applicants note that the terms "substituted" and "optionally substituted" are commonly used in claims directed to chemical compositions. Indeed, over *eleven thousand patents* recite either "heteroaryl" or "heterocycloalkyl" and "substituted" in the claims, <sup>14</sup> and over *six thousand patents* recite either "heteroaryl" or "heterocycloalkyl" and "optionally substituted" in the claims. <sup>15</sup> Accordingly, Applicants submit that one of skill in the art would understand the use of "substituted" and "optionally substituted" in combination with a chemical group. Furthermore, the USPTO Board of Appeals and Interferences has specifically held that modifiers such as "optionally" do not render a claim indefinite. <sup>16</sup>

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 112, second paragraph.

<sup>&</sup>lt;sup>13</sup> Office Action, page 4.

 $<sup>^{14}</sup>$  See Search of USPTO patent database, attached as Exhibit B.

 $<sup>^{15}</sup>$  See Search of USPTO patent database, attached as **Exhibit C**.

<sup>&</sup>lt;sup>16</sup> Ex parte Cordova, 10 USPQ2d 1949, 1950 (BPAI 1989) ("The examiner contends that the use of the term 'optionally' is ambiguous, since it is not clear whether the unsaturated aliphatic carboxylic acid is, in fact, encompassed by the claims. The recitation 'optionally' denotes that the unsaturated aliphatic carboxylic acid may or may not be employed. It is not apparent, and the examiner has not explained, why the use of such alternative language fails to particularly point out and distinctly claim the subject matter appellants regard as their invention. It is our opinion that the use of the alternative expression 'optionally' in the rejected claims does not obfuscate the subject matter appellants regard as their invention") (citing Ex parte Head, 214 USPQ 551 (BPAI 1981)).

Patent Application No. 10/560,503 Attorney Docket: 69681.000005

### **CONCLUSION**

Applicants respectfully submit that claims are in condition for allowance, and such disposition is earnestly solicited. Should the Examiner believe that any issues remain after consideration of this response, the Examiner is invited to contact the Applicants' undersigned representative to discuss and resolve such issues.

Respectfully submitted,

**HUNTON & WILLIAMS LLP** 

Dated: <u>April 30, 2009</u>

By:

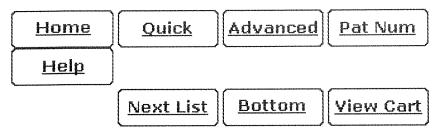
Robert M. Schulman Registration No. 31,196

Alexander H. Spiegler Registration No. 56,625

HUNTON & WILLIAMS LLP Intellectual Property Department 1900 K Street, N.W., Suite 1200 Washington, DC 20006-1109 (202) 955-1500 (telephone) (202) 778-2201 (facsimile)

# Exhibit A

### USPTO PATENT FULL-TEXT AND IMAGE DATABASE



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Results of Search in US Patent Collection db for: (ACLM/heterocycloalkyl OR ACLM/heteroaryl): 12405 patents. *Hits 1 through 50 out of 12405* 

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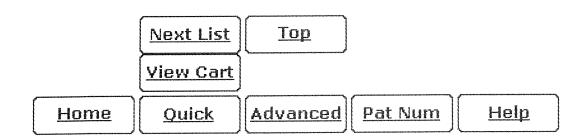
### Refine Search

aclm/heterocycloalkyl or aclm/heteroaryl

- PAT. NO. Title
- 1 7,514,710 **T** Bottom gate thin film transistors
- 2 7,514,579 T Boronic chalcone derivatives and uses thereof
- 3 7,514,566 **T** Thiazole compounds and methods of use
- 4 7,514,564 **T** Substituted amine derivatives and methods of use
- 5 7,514,558 Biphenyl derivatives
- 6 7,514,557 T Process for preparing acyclic HCV protease inhibitors
- 7 7,514,468 T Indolinone derivatives substituted in the 6 position, the preparation thereof and their use as pharmaceutical compositions
- 8 7,514,462 T .omega.-Cycloalkyl 17-heteroaryl prostaglandin E.sub.2 analogs as EP.sub.2-receptor agonists
- 9 7,514,460 T Benzazole analogues and uses thereof
- 10 7,514,459 **T** Gamma-secretase inhibitors
- 11 7,514,458 T Anti-cytokine heterocyclic compounds

- 12 7,514,452 **T** 2-furancarboxylic acid hydrazides and pharmaceutical compositions containing the same
- 13 7,514,451 **T** 7-(4-Substituted-3-cyclopropylaminomethyl-1 pyrrolidinyl) quinolonecarboxylic acid derivative
- 14 7,514,448 T Azaindoles useful as inhibitors of rock and other protein kinases
- 15 7,514,447 T Diarylamine-containing compounds and compositions, and their use as modulators of c-kit receptors
- 16 7,514,446 T Pyrimidine compounds
- 17 7,514,442 Trisubstituted 4-aminopyrazolopyrimidines as cyclin dependent kinase inhibitors
- 18 7,514,440 T Fused pyrrolocarbazoles
- 19 7,514,437 T Substituted diketopiperazines as oxytocin antagonists
- 20 7,514,436 Pyridazine derivatives and their use as therapeutic agents
- 21 7,514,435 **T** Pyrrolotriazine kinase inhibitors
- 22 7,514,434 T Heterocyclic compounds having an oxadiazole moiety and hydro isomers thereof
- 23 7.514,429 T Benzoxazinone-derived compounds, their preparation and use as medicaments
- 24 7,514,426 T Substituted imidazol[1,5-A][1,2,4]triazolo[1,5-D][1,4]benzodiazepine derivatives
- 25 7,514,422 T 5HT.sub.2c receptor modulators
- 26 7,514,419 T Phosphorus-containing thyromimetics
- 27 7,514,417 **T** A.sub.1 adenosine receptor agonists
- 28 7,514,410 T Hepatitis C therapies
- 29 7,514,409 **T** VLA-4 antagonists
- 30 7,513,918 T Agents for coloring keratin fibers comprising zwitterionic azomethine dyes
- 31 7,513,917 Coloring agents for keratin fibers
- 32 7,513,916 Agents for coloring keratin fibers
- 33 7,511,175 T Inhibitors of the 11-beta-hydroxysteroid dehydrogenase type 1 enzyme
- 34 7,511,158 T Synthesis of acyloxyalkyl carbamate prodrugs and intermediates thereof
- 35 <u>7,511,149</u> T <u>Process for the oxidation of certain substituted sulfilimines to insecticidal sulfoximines</u>
- 36 7,511,146 T 2-substituted benzimidazole piperidines analogs as selective melanin concentrating hormone receptor antagonists for the treatment of obesity and related disorders
- 37 7,511,145 **B**icyclic heteroaryl derivatives
- 38 7,511,144 T Reverse hydroxamic acid derivatives

- 39 <u>7,511,095</u> Thioester-terminated water soluble polymers and method of modifying the N-terminus of a polypeptide therewith
- 40 7,511,073 T Amines that inhibit a mammalian anandamide transporter, and methods of use thereof
- 41 7,511,070 T Compounds and therapies for the prevention of vascular and non-vascular pathologies
- 42 7,511,068 T Mercaptoimidazoles as CCR2 receptor antagonists
- 43 7,511,063 **T** High affinity quinoline-based kinase ligands
- 44 7,511,062 **T** Substituted 2-quinolyl-oxazoles useful as PDE4 inhibitors
- 45 7,511,059 T Thiazolidinones, their production and use as pharmaceutical agents
- 46 7,511,058 T Heterocyclic inhibitors of MEK and methods of use thereof
- 47 7,511,057 Triazolopyridinylsulfanyl derivatives as p38 MAP kinase inhibitors
- 48 7,511,055 **T** Naphthyridin derivatives
- 49 7,511,053 T Spiroazacyclic compounds as monoamine receptor modulators
- 50 7,511,052 T Pyrimidinyl amide compounds which inhibit leukocyte adhesion mediated by VLA-4



## Exhibit B

### USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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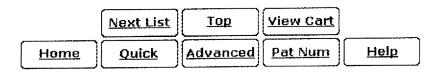
Title

NO.

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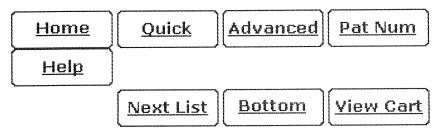
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- 46 7,511,050 T Purinone derivatives as HM74A agonists
- 47 7,511,049 T Pyrazolopyrimidines as cyclin dependent kinase inhibitors
- 48 7,511,045 T Compounds for the treatment of inflammatory diseases
- 49 7,511,043 **T** FXR modulators
- 50 7,511,042 T Triazole compounds



# Exhibit C

### USPTO PATENT FULL-TEXT AND IMAGE DATABASE



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Results of Search in US Patent Collection db for: (ACLM/"optionally substituted" AND (ACLM/heteroaryl OR ACLM/heterocycloalkyl)): 6248 patents.

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### Refine Search

aclm/"optionally substituted" and (aclm/heteroaryl or aclm

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- 30 7,511,049 T Pyrazolopyrimidines as cyclin dependent kinase inhibitors
- 31 7,511,045 T Compounds for the treatment of inflammatory diseases
- 32 7,511,043 **T** FXR modulators
- 33 7,511,042 Triazole compounds
- 34 <u>7,511,041</u> **T** <u>Fused azole-pyrimidine derivatives</u>
- 35 7,511,040 **T** Imidazopyrazines as protein kinase inhibitors
- 36 <u>7,511,039</u> **T** <u>.beta.-sheet mimetics and use thereof as inhibitors of biologically active peptides or proteins</u>
- 37 7,511,038 T Pyridazin-3(2H)-one derivatives and their use as PDE4 inhibitors
- 38 7,510,672 T Formulation for ink-jet printing comprising semiconducting polymers
- 39 7.507.832 **T** Triazole PPAR modulators
- 40 7,507,827 T Stereoselective method for the production of Clopidogrel
- 41 7,507,826 T Azaindoles useful as inhibitors of JAK and other protein kinases

- 42 7,507,767 T Cannabinoid receptor ligands
- 43 7,507,763 T Resistance-repellent retroviral protease inhibitors
- 44 <u>7,507,762</u> **T** <u>Substituted 4H-chromene and analogs as activators of caspases and inducers of apoptosis and the use thereof</u>
- 45 <u>7,507,757</u> **T** <u>Substituted heterocyclic derivatives useful as antidiabetic and antiobesity agents and method</u>
- 46 7,507,756 T Scalable synthesis of imidazole derivatives
- 47 7,507,755 **T** Inhibitors of cathepsin s
- 48 7,507,754 T EP.sub.4 receptor antagonists
- 49 7,507,732 T Cyclopentapyridine and tetrahydroquinoline derivatives
- 50 7,507,730 T Substituted pyrazolo[1,5-a]pyrimidines as potassium channel activators

